

31 August 2000

Dockets Management Branch
Food and Drug Administration
HFA-305, Room 1061
5630 Fishers Lane
Rockville, MD 20852

9276 00 SEP -6 AIO:10

SUITABILITY PETITION

The undersigned submits this Petition under Section 505 of the Federal Food, Drug and Cosmetic Act (21 USC §355), which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR §5.10. Petitioner requests the Commissioner of Food and Drugs to declare that the drug product, hereinafter described, is suitable for consideration in an abbreviated new drug application.

A. ACTION REQUIRED

By this petition, the undersigned requests permission of the Commissioner of Food and Drugs to file an abbreviated new drug application for Leucovorin Calcium Injection 5 mg (base)/mL, (preservative free) packaged in 500 mg (base)/100 mL Single-Dose Vials

B. STATEMENT OF GROUNDS

The Federal Food, Drug and Cosmetic Act as amended in 1984 provides under Section 505(j)(2)(C) that a petition may be filed with the Secretary seeking permission to file an abbreviated application for a new drug which has an active ingredient which differs from the listed drug in dosage form or **strength**. Such a petition must be granted unless the Secretary finds that investigations must be conducted to show the safety and effectiveness of the drug.

This petition requests permission to file an abbreviated new drug application for leucovorin calcium injection 5 mg (base)/mL, (preservative free), 500 mg total vial contents. The listed drug is leucovorin calcium 10 mg (base)/mL, (preservative free), available as 500 mg (base)/50 mL Single-Dose Vials..

Since the proposed product, containing leucovorin calcium 5 mg (base)/mL, would be identical in active ingredient, dosage form, and route of administration to the leucovorin calcium (preservative free) product approved under ANDA 40-147 [Abbot Laboratories], the safety and effectiveness of the proposed drug product is not expected to be different from that of the reference listed drug. Two mL of the proposed leucovorin

calcium injection 5 mg (base)/mL can be expected to be therapeutically equivalent to 1 mL of leucovorin calcium 10 mg (base)/mL marketed by Abbott.

To the best of our knowledge, the proposed strength will not be violating any patents relating to the composition of the product or the method of manufacture.

We submit that the criteria of Section 505(j)(2)(C) are met and that the requested permission to file an abbreviated new drug application for the dosage strength described above should be granted.

C. ENVIRONMENTAL IMPACT

The subject matter of this petition is covered in 21 CFR §25.23(c).

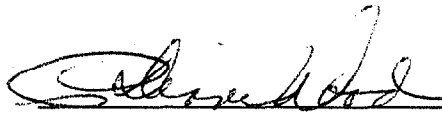
D. ECONOMIC IMPACT

The petitioner will provide this information upon request.

E. CERTIFICATION

The undersigned certifies, that, to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature:


P. Diane Wood, President

Name of Petitioner: **PD Regulatory Services, Inc.**

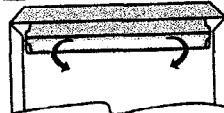
Mailing Address: **601 Route 206, Suite 26-443, Belle Mead, NJ 08502-1572**

Telephone Number: **(908) 281-6161**

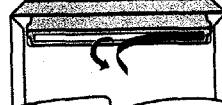
To Reuse Letter: 1. Peel off old labels



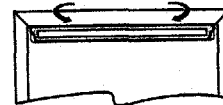
2. Fold this flap down



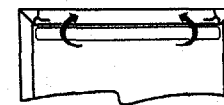
3. Expose adhesive



4. Fold top flap down



5. Press this flap up to seal



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REUSABLE

UPS Reusable Letter. Use twice, then recycle.

Place Labels in This Space

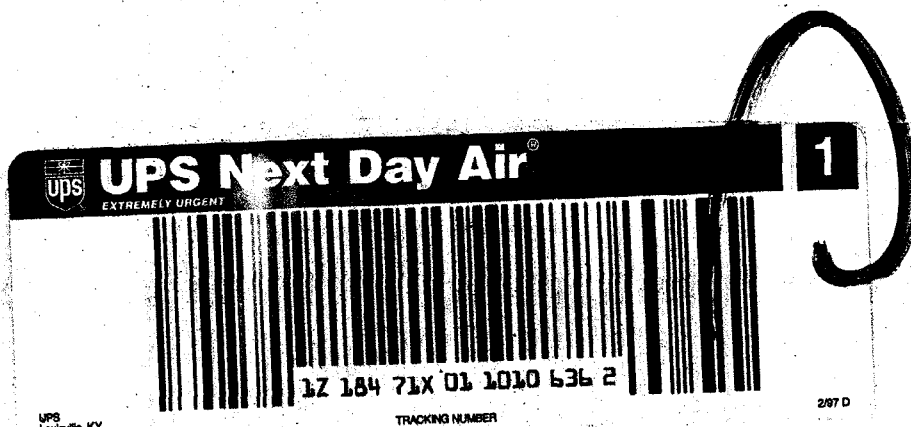
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TO

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